112TH CONGRESS
2D SESSION

S. 2292

To promote accountability, transparency, innovation, efficiency, and timeliness at the Food and Drug Administration for America's patients.

IN THE SENATE OF THE UNITED STATES

APRIL 17, 2012

Mr. BURR (for himself and Mr. COBURN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To promote accountability, transparency, innovation, efficiency, and timeliness at the Food and Drug Administration for America's patients.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Promoting Accountability, Transparency, Innovation, Efficiency, and Timeliness at FDA Act of 2012'' or the ''PATIENTS' FDA Act''.

SEC. 2. TABLE OF CONTENTS.

The table of contents for this Act is as follows:

TITLE I—ENSURING GREATER TRANSPARENCY AND ACCOUNTABILITY IN FDA REGULATORY DECISIONMAKING

SEC. 101. ADVANCING REGULATORY SCIENCE TO PROMOTE PUBLIC HEALTH AND INNOVATION.

(a) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall develop a strategy and implementation plan for advancing regulatory science for medical products in order to promote the public health and advance innovation in regulatory decisionmaking.

(b) REQUIREMENTS.—The strategy and implementation plan developed under subsection (a) shall be consistent with the user fee performance goals in the Prescription Drug User Fee Agreement commitment letter, the Generic Drug User Fee Agreement commitment letter, and the Biosimilar User Fee Agreement commitment letter transmitted by the Secretary to Congress on January 13, 2012, and the Medical Device User Fee Agreement published in the Federal Register on March 20, 2012, and shall—

(1) identify a clear vision of the fundamental role of efficient, consistent, and predictable, science-

based decisions throughout regulatory decision-making of the Food and Drug Administration with respect to medical products;

(2) identify the regulatory science priorities of the Food and Drug Administration directly related to fulfilling the mission of the agency with respect to decisionmaking concerning medical products and allocation of resources towards these regulatory science priorities;

(3) identify regulatory and scientific gaps that impede the timely development and review of, and regulatory certainty with respect to, the approval, licensure, or clearance of medical products, including with respect to companion products and new technologies, and facilitating the timely introduction and adoption of new technologies and methodologies in a safe and effective manner;

(4) identify clear, measurable metrics by which progress on the priorities identified under paragraph (2) and gaps identified under paragraph (3) will be measured by the Food and Drug Administration, including metrics specific to the integration and adoption of advances in regulatory science described in paragraph (5) and improving medical product deci-

sionmaking, in a predictable and science-based manner; and

(5) set forth how the Food and Drug Administration will ensure that advances in regulatory science for medical products are adopted, as appropriate, on an ongoing basis and in an manner integrated across centers, divisions, and branches of the Food and Drug Administration, including by senior managers and reviewers, including through the—

(A) development, updating, and consistent application of guidance documents that support medical product decisionmaking; and

(B) the adoption of the tools, methods, and processes under section 566 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–5).

(c) ANNUAL PERFORMANCE REPORTS.—As part of the annual performance reports by the Food and Drug Administration to Congress, the Secretary shall annually report on the progress made with respect to—

(1) advancing the regulatory science priorities and resolving the gaps identified under paragraph (3) of subsection (b), including reporting on specific metrics identified under paragraph (4) of such subsection;

(2) the integration and adoption of advances in regulatory science as set forth in paragraph (5) of such subsection; and

(3) the progress made in advancing the regulatory science goals outlined in the Prescription Drug User Fee Agreement commitment letter, the Generic Drug User Fee Agreement commitment letter, and the Biosimilar User Fee Agreement commitment letter transmitted by the Secretary to Congress on January 13, 2012, and the Medical Device User Fee Agreement published in the Federal Register on March 20, 2012.

(d) INDEPENDENT ASSESSMENT.—Not later than January 1, 2016, the Comptroller General of the United States shall submit to Congress a report—

(1) detailing the progress made by the Food and Drug Administration in meeting the priorities and addressing the gaps identified in subsection (b), including any outstanding gaps; and

(2) containing recommendations, as appropriate, on how regulatory science initiatives for medical products can be strengthened and improved to promote the public health and advance innovation in regulatory decisionmaking.

(e) MEDICAL PRODUCT.—In this section, the term ''medical product'' means a drug, as defined in subsection (g) of section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321), a device, as defined in subsection (h) of such section, or a biological product, as defined in section 351(i) of the Public Health Service Act (42 U.S.C. 262(i)).

SEC. 102. REPORTING WITH RESPECT TO PRESCRIPTION DRUGS.

Section 736B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h–2) is amended—

(1) by amending subsection (a) to read as follows:

''(a) PERFORMANCE REPORT.—Beginning with fiscal year 2013, not later than 120 days after the end of each fiscal year for which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Health Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report concerning—

''(1) the progress of the Food and Drug Administration in achieving the goals identified in the document entitled, 'PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2013 through 2017', and included in the Prescription

Drug User Fee Agreement commitment letter transmitted by the Secretary to Congress on January 13, 2012, during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals; and

''(2) the progress of each review division and branch within the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research in achieving such goals, and the plans of each such division and branch for meeting the goals, including—

''(A) the number of applications for approval of a new drug under section 505(b) of this Act or a new biological product under section 351(a) of the Public Health Service Act filed per fiscal year by each review division and branch;

''(B) the number of such applications that did not meet the goals described in paragraph (1);

''(C) the percentage of such applications approved by each review division and branch;

''(D) the percentage of such applications found to be approvable by each review division and branch;

"(E) the percentage of such applications that were issued complete response letters by each review division and branch;

"(F) the percentage of such applications that were subject to a refuse-to-file action by each review division and branch;

"(G) the percentage of such applications withdrawn by each review division and branch;

"(H) the total number of review cycles per such approval and the average, mean, and median number of review cycles per such application by each review division and branch;

"(I) the mean and median time to final decision, including approval, per such application by each review division and branch;

"(J) the average total time to decision by each review division and branch, including the number of days spent during the review by the Food and Drug Administration and days spent by the sponsor responding to a complete response letter;

"(K) the percentage of applications that are considered as fast track products under section 506 and through accelerated approval by each review division and branch; and

''(L) the number of full-time equivalent positions and overall budget assigned to each review division and branch.

''(b) INCLUSION.—The report under this section for a fiscal year shall include information on all previous cohorts for which the Secretary has not given a complete response on all human drug applications and supplements in the cohort.''; and

(2) in subsection (b), by inserting '', including a qualitative and quantitative report with respect to how user fees and appropriated funds are used for the drug review process, including the percentage of review time devoted to activities related to the review of applications under subsections (b) and (j) of section 505 and subsections (a) and (k) of section 351 of the Public Health Service Act'' before the period at the end.

SEC. 103. REPORTING WITH RESPECT TO GENERIC DRUGS.

Part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g et seq.) is amended by adding at the end the following:

''SEC. 736C. REPORTING WITH RESPECT TO GENERIC DRUGS.

''(a) IN GENERAL.—Beginning with fiscal year 2013, not later than 120 days after the end of each fiscal year

for which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Health Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report concerning—

''(1) the progress of the Food and Drug Administration in achieving the goals identified in the Generic Drug User Fee Act (GDUFA) proposal of the Food and Drug Administration, as set forth in the Generic Drug User Fee Agreement commitment letter dated January 13, 2012, during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals; and

''(2) the progress of the Office of Generic Drugs within the Center for Drug Evaluation and Research and the Office of Regulatory Affairs in achieving such goals, and the plans of the Office of Generic Drugs, the Center for Drug Evaluation and the Office of Regulatory Affairs in meeting the goals, including—

''(A)(i) the progress in completing review of applications under section 505(j) of the Federal Food, Drug, and Cosmetic Act, amendments to such applications, and prior approval supplements with respect to such applications

that have been pending for more than 10 months, including applications under section 505(j) that have been pending for more than 10 months as of October 1, 2012, and prior approval supplements to such applications that have been pending for more than 180 days as of October 1, 2012;

''(ii) the total number of applications under section 505(j), amendments to such applications, and prior approval supplements with respect to such applications that have been pending for more than 10 months; and

''(iii) the average total time it takes to review and reach a final decision on—

''(I) applications under section 505(j);

''(II) major and minor amendments to applications under section 505(j); and

''(III) prior approval supplements with respect to applications under section 505(j);

''(B) the number of such applications that did not meet the goals described in paragraph (1);

''(C) the total number of review cycles per approval of an application described in sub-

clause (I), (II), or (III) of subparagraph (A)(iii) and the average, mean, and median number of review cycles per such application by each review division and branch;

"(D) the number of meetings granted to industry and the number of meeting requests submitted by industry;

"(E) the mean and median time to final decision, including approval, per such application by the Office of Generic Drugs;

"(F) the median time frames and ranges for reporting decisions with respect to good manufacturing practices to the Office of Generic Drugs following completion of inspections;

"(G) the median time frames for completing requested foreign and domestic inspections;

"(H) the total number of review cycles per such approval and the average, mean, and median number of review cycles per such application;

"(I) the average total time to decision by the Office of Generic Drugs, including the number of days spent during the review by the Food

and Drug Administration and days spent by the sponsor responding to a complete response; and

''(J) the number of full-time equivalent positions and overall budget assigned to the Office of Generic Drugs and each unit of the Food and Drug Administration.

''(b) INCLUSION.—The report under this section for a fiscal year shall include information on all previous cohorts for which the Secretary has not given a complete response on all human drug applications and supplements in the cohort.

''(c) FISCAL REPORT.—Beginning not later than fiscal year 2013, not later than 120 days after the end of each fiscal year, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on the implementation of the authority for any user fees with respect to generic drugs during such fiscal year, and the use, by the Food and Drug Administration, of any such fees collected for such fiscal year, including a qualitative and quantitative report with respect to how user fees and appropriated funds are used for the drug review process, including the percentage of review time devoted to direct review of applications under section (j) of section 505.''.

SEC. 104. REPORTING WITH RESPECT TO BIOSIMILARS.

Part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g et seq.), as amended by section 103, is further amended by adding at the end the following:

"SEC. 736D. REPORTING WITH RESPECT TO BIOSIMILARS.

''(a) PERFORMANCE REPORT.—Beginning with fiscal year 2013, not later than 120 days after the end of each fiscal year for which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report concerning—

''(1) the progress of the Food and Drug Administration in achieving the goals identified in the Biosimilars User Fee Act (BSUFA) proposal of the Food and Drug Administration, as set forth in the Biosimilar User Fee Agreement commitment letter dated January 13, 2012, during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals; and

''(2) the progress of each review division and branch within the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research in achieving the goals, and the plans

of each such division and branch for meeting the goals, including—

"(A) the number of applications for approval under section 351(k) of the Public Health Service Act filed per fiscal year by each review division and branch;

"(B) the number of such applications that did not meet the goals described in paragraph (1) and the total time elapsed since such applications were submitted, including the time such application was with the Food and Drug Administration and the time such application was with the sponsor;

"(C) the percentage of such applications approved by each review division and branch;

"(D) the percentage of such applications that were issued complete response letters by each review division and branch;

"(E) the percentage of such applications that were subject to a refuse-to-file action by each review division and branch;

"(F) the percentage of such applications withdrawn by the sponsor by each review division and branch;

''(G) the total number of review cycles per each approval and the average, mean, and median review cycles per such application (or for all approvals) by each review division and branch;

''(H) the mean and median time to final decision, including approval, per such application by each review division and branch; and

''(I) the number of full-time equivalent positions and overall budget assigned to each review division and branch.

''(b) INCLUSION.—The report under this subsection for a fiscal year shall include information on all previous cohorts for which the Secretary has not given a complete response on all applications under section 351(k) of the Public Health Service Act in the cohort.

''(c) FISCAL REPORT.—Beginning not later than fiscal year 2013, not later than 120 days after the end of each fiscal year, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House a report on the implementation of the authority for any user fees with respect to biological products approved under section 351(k) of the Public Health Service Act during such fiscal year, and the use,

by the Food and Drug Administration, of any such fees collected for such fiscal year, including a qualitative and quantitative report with respect to how user fees and appropriated funds are used for the drug review process, including the percentage of review time devoted to direct review of applications under subsections (a) and (k) of section 351 of the Public Health Service Act.''.

SEC. 105. DOCUMENTATION OF REGULATORY DECISIONS.

Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by adding at the end the following:

''SEC. 524A. AGENCY DOCUMENTATION OF SIGNIFICANT DECISIONS REGARDING DRUGS AND DEVICES.

''(a) DOCUMENTATION OF RATIONALE FOR SIGNIFICANT DECISIONS.—The Secretary shall document the scientific and regulatory rationale for any significant decision—

''(1) of the Center for Drug Evaluation and Research regarding an application under subsection (b) or (j) of section 505;

''(2) of the Center for Biologics Evaluation and Research regarding an application under subsection (a) or (k) of section 351 of the Public Health Service Act; and

''(3) of the Center for Devices and Radiological Health regarding submission or review of a report under section 510(k), an application under section 515, or an application for an exemption under section 520(g).

''(b) PROVISION OF DOCUMENTATION.—Upon request, the Secretary shall furnish such documentation to the person who is seeking to submit, or who has submitted, such report or application.''.

SEC. 106. REVIEW OF REGULATIONS AND GUIDANCE.

Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services shall review all regulations and guidance of the Food and Drug Administration with respect to human medical products (as defined in section 101) to ensure consistency with—

(a) the requirements of the Federal, Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.); and

(b) the regulatory principles of the benefits of such regulations and guidance justifying the costs and adoption of the least burdensome approaches to such regulation and guidance as outlined in Executive Order 13563, dated January 18, 2011.

SEC. 107. LEVERAGING INFORMATION TECHNOLOGY TO FULFILL FDA'S PUBLIC HEALTH MISSION.

(a) HHS REPORT.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services shall—

(1) report to Congress on—

(A) the milestones and a completion date for developing and implementing a comprehensive information technology strategic plan to align the information technology systems modernization projects with the strategic goals of the Food and Drug Administration, including results-oriented goals, strategies, milestones, performance measures;

(B) efforts to finalize and approve a comprehensive inventory of the information technology systems of the Food and Drug Administration that includes information describing each system, such as costs, system function or purpose, and status information, and incorporate use of the system portfolio into the information investment management process of the Food and Drug Administration;

(C) the ways in which the Food and Drug Administration uses the plan described in subparagraph (A) to guide and coordinate the

modernization projects and activities of the Food and Drug Administration, including the interdependencies among projects and activities; and

(D) the extent to which the Food and Drug Administration has fulfilled or is implementing recommendations of the Government Accountability Office with respect to the Food and Drug Administration and information technology; and

(2) develop—

(A) a documented enterprise architecture program management plan that includes the tasks, activities, and timeframes associated with developing and using the architecture and addresses how the enterprise architecture program management will be performed in coordination with other management disciplines, such as organizational strategic planning, capital planning and investment control, and performance management; and

(B) a skills inventory, needs assessment, gap analysis, and initiatives to address skills gaps as part of a strategic approach to information technology human capital planning.

(b) GAO REPORT.—Not later than January 1, 2016, the Comptroller General of the United States shall issue a report regarding the strategic plan described in subsection (a) and related actions carried out by the Food and Drug Administration. Such report shall assess the progress the Food and Drug Administration has made on—

(1) the development and implementation of a comprehensive information technology strategic plan, including the results-oriented goals, strategies, milestones, and performance measures identified in subparagraph (a);

(2) the effectiveness of the comprehensive information technology strategic plan in subparagraph (a), including the results-oriented goals and performance measures; and

(3) the extent to which the Food and Drug Administration has fulfilled recommendations of the Government Accountability Office with respect to such agency and information technology.

TITLE II—RECALIBRATING RISK-BENEFIT CONSIDERATIONS

SEC. 201. DEVICES.

Section 513(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(a)) is amended—

(1) in paragraph (2)—

(A) by redesignating subparagraphs (A) through (C) as clauses (i) through (iii), respectively,

(B) by striking ''(2) For'' and inserting ''(2)(A) For''; and

(C) by adding at the end the following:

''(B) The Secretary shall assess the safety and effectiveness of a device as required under subparagraph (A) from the perspective of a reasonable patient in the intended use population who would assign the most value to the effect the device purports to have or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling, and who would be willing to accept the probable risks that may be associated with the use of the device as prescribed, recommended, or suggested in the labeling or proposed labeling.'';

(2) by redesignating paragraph (3) as paragraph (4); and

(3) by inserting after paragraph (2) the following:

''(3)(A) The safety of a device is, for purposes of this section and sections 514 and 515, to be de-

termined in accordance with regulations promulgated by the Secretary, on the basis of information contained in the application and valid scientific evidence derived from well-controlled investigations. The Secretary shall not find a lack of reasonable assurance of safety unless information contained in the application or valid scientific evidence demonstrates that there is a reasonable probability of a risk of injury or illness from the proposed use of the device that is not outweighed by the probable benefit to health from the device.

''(B) The Secretary may determine there is not reasonable assurance of safety with respect to a device only after identifying in writing—

''(i) the probable risk of injury or illness;

''(ii) the scientific evidence that reasonably supports the Secretary's determination; and

''(iii) the type of data or information, consistent with the least burdensome provisions of this Act, that would demonstrate a benefit that would exceed the probable risk.''.

SEC. 202. DRUGS.

Section 505(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(d)) is amended by adding at the end the following:

''In assessing the safety and effectiveness of a drug under this subsection, the Secretary shall implement a structured benefit-risk assessment framework in the new drug approval process to facilitate the balanced consideration of benefits and risks, a consistent and systematic approach to the discussion and regulatory decisionmaking, and the communication of the benefits and risks of new drugs.''.

TITLE III—REDUCING UNNECESSARY DELAYS AND REGULATORY BURDENS

SEC. 301. OPTIMIZING GLOBAL CLINICAL TRIALS.

Subchapter E of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb et seq.) is amended by adding at the end the following:

''SEC. 568. OPTIMIZING GLOBAL CLINICAL TRIALS.

''For purposes of eliminating costly and scientifically unnecessary clinical trials, enhancing the efficiency of medical products development, and facilitating the Food and Drug Administration and the acceptance of foreign clinical data of other health authorities, the Food and Drug Administration shall—

''(1) work with other regulatory authorities of similar standing, medical research companies, and international organizations to foster and encourage

uniform, scientifically-driven clinical trial standards around the world; and

''(2) enhance the commitment to provide the least burdensome, consistent parallel scientific advice to manufacturers seeking simultaneous global development of new medical products in order to minimize the need for conduct and duplication of clinical studies, preclinical studies, or non-clinical studies.''.

SEC. 302. ADVANCING AMERICAN PATIENTS' TIMELY ACCESS TO INNOVATIVE DEVICES.

Section 520(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(g)) is amended by adding at the end the following:

''(8) In the case of a person intending to investigate the safety or effectiveness of a class II or a class III device that—

''(A) has a valid marketing authorization by the appropriate authority in Australia, Canada, Israel, Japan, New Zealand, Switzerland, or South Africa or in the European Union or a country in the European Economic Area (the countries in the European Union and the European Free Trade Association), or such other authority recognized by the Secretary; and

''(B) has a history of use pursuant to its marketing authorization with no device-related serious unanticipated adverse event reports,

the Secretary shall permit an exemption for clinical testing of such device for the purpose of developing data to obtain clearance or approval for the commercial distribution of such device.''.

SEC. 303. ENSURING LEGAL SUFFICIENCY AND CONSISTENCY OF FDA ENFORCEMENT POLICIES.

Subchapter E of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb et seq.), as amended by section 301, is further amended by adding at the end the following:

''SEC. 569. WARNING LETTERS.

''(a) IN GENERAL.—Before a warning letter with respect to a drug or device is issued, the Office of the Chief Counsel shall review such warning letter to ensure that such warning letter is legally sufficient and consistent with all policies of the Food and Drug Administration.

''(b) WARNING LETTER.—For purposes of this section, the term 'warning letter' shall include all notices of alleged violations, including untitled letters.''.

TITLE IV—STRENGTHENING ADVISORY COMMITTEES FOR PATIENTS

SEC. 401. STRENGTHENING ADVISORY COMMITTEES FOR PATIENTS.

(a) FINDING.—Congress finds that—

(1) as science becomes more specialized, it becomes more difficult for general scientists to keep up with the scientific advances in the many areas that the Food and Drug Administration regulates;

(2) it is necessary for the Food and Drug Administration to be able to draw upon essential medical and scientific expertise across specialized areas in order to fulfill its public health mission;

(3) the programs with respect to advisory committees under the Food and Drug Administration should be strengthened and improved to ensure that the Food and Drug Administration is able to be advised by the most qualified medical and scientific subject experts; and

(4) an appropriate balance should be restored with respect to conflict of interest considerations for advisory committees and experts advising the Food and Drug Administration to ensure that the Food

and Drug Administration is able to draw upon the most qualified medical and scientific experts.

(b) ADVISORY COMMITTEES AND SPECIAL GOVERNMENT EMPLOYEES.—Subchapter A of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371 et seq.) is amended by adding at the end the following:

"SEC. 714. STRENGTHENING ADVISORY COMMITTEES.

''(a) INCREASING NUMBERS OF MEDICAL AND SCIENTIFIC SPECIALISTS PROVIDING EXPERTISE AND ANNUAL REPORT.—

''(1) SPECIAL GOVERNMENT EMPLOYEES.—In this section, the term 'special Government employee' has the meaning given the term in section 202 of title 18, United States Code.

''(2) INCREASING NUMBERS.—The Secretary, acting through the Commissioner of Food and Drugs, shall collaborate with stakeholders, including consumer groups, patient groups, academia, and industry representatives, to increase the number of special Government employees across medical and scientific specialties in areas where the Secretary lacks specific scientific, medical, or technical expertise necessary for the performance of its regulatory responsibilities.

''(3) ANNUAL REPORTS.—The Secretary, acting through the Commissioner of Food and Drugs, shall submit an annual report, as part of the annual user fee agreement performance report, on the management of the pool of special Government employees of the Food and Drug Administration by citing—

''(A) the total number of such employees;

''(B) the employees' specific areas of expertise;

''(C) the turnover by resignation of such employees;

''(D) new special Government employee appointments;

''(E) the frequency of participation by special Government employees in decisions by the Food and Drug Administration or advice provided to the Food and Drug Administration; and

''(F) the total number of applicants not selected to serve as special government employees.

''(b) TEMPLATE FOR ADVISORY COMMITTEE BYLAWS.—The Secretary, acting through the Commissioner of Food and Drugs, shall—

''(1) publish a standardized template for the bylaws of advisory committees established under this Act; and

''(2) require each of such advisory committees to compile and publish online an annual report containing, at a minimum—

''(A) a list of the members of the advisory committee, the business address of each member, and the dates of each member's term;

''(B) a list of the Chair and any other designated leaders of the Advisory Committee;

''(C) a list of any vacancies on the advisory committee and the length of any vacancy;

''(D) the advisory committee's functions, expenditures, the dates and places of meetings, and the attendance of members present at such meetings; and

''(E) a summary of the advisory committee's activities and recommendations made during the fiscal year.

''(c) TEMPLATE FOR PUBLICATION OF CVS.—

''(1) IN GENERAL.—The Secretary, acting through the Commissioner of Food and Drugs, shall collaborate with stakeholders, including consumer groups, patient groups, academia, and industry rep-

resentatives, to publish a standardized template as guidance for special Government employees of the Food and Drug Administration and members of advisory committees established under this Act to use in publicizing their curriculum vitae.

''(2) CONTENT OF TEMPLATE.—The standardized template described in paragraph (1) shall be consistent with the following:

''(A) Peer-reviewed research shall be separated from non-peer-reviewed research.

''(B) The template shall include a separate list of research that has been submitted for review but not yet published.

''(C) The template shall include a separate list of non-research publications.

''(D) The template shall include general information about the topic and date in cases where the research or grant subject matter has been redacted.

''(E) All items shall be listed in chronological order beginning with the most recent.

''(d) AFFIDAVITS.—The Secretary may require members of advisory committees established under this Act to sign an affidavit stating that the member has read the majority of the briefing materials pertinent to the decision

or advice and agrees to the code of conduct to serve as a special government employee.

''(e) REPORT.—

''(1) IN GENERAL.—Not later than January 1, 2017, the Secretary, acting through the Commissioner of Food and Drugs, shall report to Congress on the issue of temporary members serving on advisory committees established under this Act.

''(2) CONTENT OF REPORT.—The report described in paragraph (1) shall include the following information:

''(A) How many temporary members have served on advisory committees established under this Act and how many temporary members served on each advisory committee.

''(B) What percentage of such temporary members were called upon to offer subject matter expertise in voting or to reach a quorum.

''(C) Whether temporary members offer expertise on an issue being decided.

''(D) Whether temporary members being called upon merely to reach a quorum.

''(E) How temporary members are selected.''.

TITLE V—MEDICAL DEVICE REGULATORY IMPROVEMENTS

Subtitle A—Premarket Predictability

SEC. 501. TRACKING AND REVIEW OF APPLICATIONS FOR INVESTIGATIONAL DEVICE EXEMPTIONS.

Section 520(g) (21 U.S.C. 360j(g)) is amended by adding at the end the following:

''(8)(A) Upon the submission of an application for an exemption for a device under this subsection, the submission of a request to classify a device under section 513, or the submission of a report for a device under section 510(k), whichever occurs first, the Secretary shall assign a tracking number to the device.

''(B) The Secretary shall use such tracking number to record the following interactions between the Secretary and applicant with respect to the device:

''(i) Submission or approval of an application for an exemption under this subsection.

''(ii) Submission of a request to classify the device under section 513.

''(iii) Submission or clearance of a report under section 510(k).

''(iv) Any meeting or meeting request, including in anticipation of the submission of such an application or report.

''(v) Submission or approval of an application under section 515(c).

''(vi) Any formal or informal request by the Secretary for additional information.

''(vii) Any deficiency letter.

''(viii) Any response by the applicant to a request described in clause (v) or a deficiency letter.

''(ix) Any written submission by the applicant to the Food and Drug Administration.

''(x) Any other matter, as determined appropriate by the Secretary.

''(9) Upon the submission of an application for an exemption under this subsection for a device, the Secretary shall assign, to review the application, a reviewer with prior review experience with that type of device or technology or other relevant expertise.''.

SEC. 502. INVESTIGATIONAL DEVICE EXEMPTIONS.

Section 520(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(g)) is amended—

(1) in paragraph (2)(B)(ii), by inserting ''safety and effectiveness'' after ''Secretary of''; and

(2) in paragraph (4), by adding at the end the following:

''(C) Consistent with paragraph (1), the Secretary shall not disapprove an application under this subsection because the Secretary determines—

''(i) that the investigation may not support a substantial equivalence or de novo classification determination or approval of the device;

''(ii) that the investigation may not meet a requirement, including a data requirement, relating to the approval or clearance of a device; or

''(iii) that an additional or different investigation may be necessary to support clearance or approval of the device.''.

SEC. 503. DEVICE SUBMISSION ACCEPTANCE CRITERIA.

(a) IN GENERAL.—To ensure more efficient and timely evaluation of devices, the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall revise the device submission acceptance criteria utilized by the Secretary under chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et

seq.) as in effect on the date of enactment of this Act and implement such revised criteria.

(b) DESCRIPTION; CONTENT.—

(1) DESCRIPTION.—The revised acceptance criteria described under subsection (a) shall be objective and consistent with the Federal Food, Drug, and Cosmetic Act and regulations issued under such Act (as in effect on the date of enactment of this Act).

(2) CONTENT.—Under such revised criteria, the Secretary's decision to refuse to accept or file a device submission shall be consistent with the requirements for such submission as set forth in the Federal Food, Drug, and Cosmetic Act and the regulations issued under such Act (as in effect on the date of enactment of this Act), and shall not be based on criteria inconsistent with the Federal Food, Drug, and Cosmetic Act or such regulations.

(c) REPORT.—Not later than 2 years after the date of enactment of this Act, the Comptroller General of the United States shall issue a report regarding the device submission acceptance criteria. The Comptroller General shall, in consultation with persons accredited under section 523 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360m), assess and report on the clarity of the

revised device submission acceptance criteria under this section, and the effectiveness of the outcome measures adopted by the Center for Device and Radiological Health to ensure the consistent, appropriate, and predictable application of such device submission acceptance criteria consistent with the Federal Food, Drug, and Cosmetic Act and regulations issued under such Act (as in effect on the date of enactment of this Act).

SEC. 504. TRANSPARENCY IN CLEARANCE PROCESS.

(a) PUBLICATION OF DETAILED DECISION SUMMARIES.—Section 520(h) (21 U.S.C. 360j(h)) is amended by adding at the end the following:

''(5) Subject to subsection (c) and section 301(j), the Secretary shall regularly publish detailed decision summaries for each clearance of a device under section 510(k).''.

(b) APPLICATION.—The requirement of section 520(h)(5) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), applies only with respect to clearance of a device occurring after the date of the enactment of this Act.

SEC. 505. RESTORING REGULATORY CERTAINTY WITH RESPECT TO 510(k) REPORTS REQUIRED FOR CERTAIN MODIFICATIONS.

(a) IN GENERAL.—Section 510(n) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(n)) is amended—

(1) by striking ''(n) The Secretary'' and inserting ''(n)(1) The Secretary''; and

(2) by adding at the end the following:

''(2) A report under subsection (k) is not required for a modification to a device that has been classified into class I or II under subsection (f)(1) or (i) of section 513 if—

''(A) the change is—

''(i) validated by same method applied to the classified device undergoing modification, or a current validation method that is equivalent to the validation method applied to the device undergoing modification;

''(ii) the validation identified under clause (i) includes all changes to the last version of the device that the Secretary found substantially equivalent to a predicate device, within the meaning of subsections (f)(1) and (i) of section 513; and

''(iii) the validation of the modified device reveals that the safety and effectiveness results are consistent with the validation results of the unmodified device;

''(B) the device's intended use remains the same; and

''(C) the information identified under subparagraphs (A) and (B) is documented and maintained as part of the design file subject to inspection by the Secretary under section 704(a) for a period of time equal to the design life of the device, or 2 years from the date of the first commercial distribution of the modified device, whichever occurs later.''.

(b) REGULATIONS.—Not later than 1 year after the date of the enactment of this Act, the Secretary shall promulgate a final regulation to implement section 510(n)(2) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), including to define the phrase ''significantly affect the safety or effectiveness of the device'' consistent with the substantive criteria of clauses (i) through (iii) of section 510(n)(2)(A).

(c) ANNUAL REPORT.—The Secretary shall annually submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report

that specifies, with respect to the preceding 2-year period—

(1) the number of reports submitted under subsection 510(k) for a modification or change to a device that was cleared under such subsection prior to such modification or change; and

(2) the number of such reports submitted in response to—

(A) a request from the Secretary,

(B) an observation made by the Secretary during an inspection of an applicant's facility; or

(C) any other enforcement action initiated by the Secretary.

SEC. 506. MEETING THE DEVICE NEEDS OF INDIVIDUAL PATIENTS.

Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 515A the following:

"SEC. 515B. MEETING THE DEVICE NEEDS OF INDIVIDUAL PATIENTS.

"(a) CUSTOM DEVICES.—Sections 514 and 515 shall not apply to any device modified to meet the individual needs of a specific patient if such device—

''(1) in order to comply with the order of an individual physician or dentist (or any other specially qualified person designated under regulations promulgated by the Secretary after an opportunity for an oral hearing), necessarily deviates from an otherwise applicable performance standard or requirement prescribed by or under section 515;

''(2) is not generally available in the United States in finished form and no other devices are domestically available to treat the unique pathology or physiological condition of the specific patient;

''(3) is intended to meet the special needs of such physician or dentist (or other specially qualified person so designated)—

''(A) in the course of the professional practice of such physician or dentist (or other specially qualified person so designated);

''(B) the need for which has been documented in the patient's medical record by such physician or dentist (or other specially qualified person so designated); and

''(C) is for use by the individual patient described in subparagraph (B); and

''(4) is—

''(A) assembled from components or manufactured on a case-by-case basis;

''(B) premanufactured and finished on a case-by-case basis; or

''(C) a modification to an existing, legally marketed device.

''(b) LIMITATIONS.—Subsection (a) shall apply to a device only if—

''(1) such device includes particular features to accommodate a specific patient's unique anatomical, physiological, or clinical needs;

''(2) such device is for the purpose of treating sufficiently rare patient conditions, such that conducting clinical investigations would be impractical; and

''(3) production of such device is limited to no more than 10 units per year of a particular device meeting a specific patient need or exhibiting a specific feature.''.

Subtitle B—FDA Renewing Efficiency From Outside Reviewer Management

SEC. 511. PERSONS ACCREDITED TO REVIEW REPORTS UNDER SECTION 510(k) AND MAKE RECOMMENDATIONS FOR INITIAL CLASSIFICATION.

(a) TIME PERIOD FOR REVIEW OF RECOMMENDATIONS OF ACCREDITED PERSONS.—Section 523(a) (21 U.S.C. 360m(a)) is amended—

(1) in paragraph (1), by striking ''reviewing reports'' and inserting ''reviewing, and making recommendations to the Secretary regarding, reports''; and

(2) in paragraph (2), by amending subparagraph (B) to read as follows:

''(B) TIME PERIOD FOR REVIEW.—Not later than 30 days after the date on which the Secretary is notified under subparagraph (A) by an accredited person with respect to a recommendation regarding a report submitted under section 510(k) or an initial classification of a device, the Secretary shall make a determination with respect to the recommendation.''.

(b) ACCESS TO DEVICE INFORMATION.—Section 523(a)(2) (21 U.S.C. 360m(a)(2)), as amended by subsection (a)(2), is amended by adding at the end the following:

"(D) ACCESS TO DEVICE INFORMATION.—

"(i) IN GENERAL.—Subject to section 301(j), for the purpose of providing accredited persons with additional information to review reports submitted under section 510(k) and make recommendations regarding the initial classification of devices, the Secretary shall regularly publish—

"(I) detailed decision summaries for each substantial equivalence determination under section 513(f)(1) and each initial classification under section 513(f)(2); and

"(II) total product life cycles information for each device classified under section 513(f).

"(ii) REQUIREMENT.—Any information published under this subparagraph shall be consistent with the requirements of part 20 of title 21, Code of Federal

Regulations (or any successor regulations).''.

(c) ACCREDITATION.—Section 523(b) (21 U.S.C. 360m(b)) is amended—

(1) in paragraph (2)—

(A) in the heading of subparagraph (C), by inserting ''AND TRAINING'' after ''AUDITING'';

(B) in subparagraph (C)—

(i) in clause (i), by striking ''and'' at the end;

(ii) by redesignating clause (ii) as clause (iii); and

(iii) by inserting after clause (i) the following:

''(ii) provide for the initial training and periodic updating of training of such person; and''; and

(C) by adding at the end the following:

''(E) PERIODIC REACCREDITATION.—

''(i) PERIOD.—Subject to suspension or withdrawal under subparagraph (B), any accreditation under this section shall be valid for a period of 3 years after its issuance.

''(ii) RESPONSE TO REACCREDITATION REQUEST.—Upon the submission of a request by an accredited person for reaccreditation under this section, the Secretary shall approve or deny such request not later than 60 days after receipt of the request.

''(iii) CRITERIA.—Not later than 120 days after the date of the enactment of this subparagraph, the Secretary shall establish and publish in the Federal Register criteria to reaccredit or deny reaccreditation to persons under this section. The reaccreditation of persons under this section shall specify the particular activities under subsection (a) for which such persons are reaccredited.'';

(2) in paragraph (3)—

(A) in subparagraph (A), by inserting ''a sole practitioner or'' after ''may not be'';

(B) in subparagraph (B), by striking ''such a manufacturer, supplier, or vendor'' and inserting ''a manufacturer, supplier, or vendor of devices of the type for which such person is accredited''; and

(C) in subparagraph (D), by striking ''devices'' and inserting ''devices of the type for which such person is accredited'';

(3) by striking paragraph (4) (relating to selection of accredited persons); and

(4) by redesignating paragraph (5) as paragraph (4).

(d) DURATION OF AUTHORITY.—Section 523(c) (21 U.S.C. 360m(c)) is amended by striking ''October 1, 2012'' and inserting ''October 1, 2017''.

(e) REPORT.—Section 523(d) (21 U.S.C. 360m(d)) is amended by striking ''January 10, 2007'' and inserting ''January 15, 2015''.

SEC. 512. PERSONS ACCREDITED TO CONDUCT INSPECTIONS.

Section 704(g)(11) (21 U.S.C. 374(g)(11)) is amended by striking ''October 1, 2012'' and inserting ''October 1, 2017''.

TITLE VI—STRENGTHENING MANAGEMENT TO SUPPORT FDA'S PUBLIC HEALTH MISSION

SEC. 601. INTEGRATED STRATEGY AND MANAGEMENT PLAN.

(a) STRATEGIC INTEGRATED MANAGEMENT PLAN.—Not later than 1 year after the date of enactment of this Act, the Secretary shall submit to Congress a strategic integrated management plan for the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, and the Center for Devices and Radiological Health. Such strategic management plan shall—

(1) identify strategic institutional goals and priorities for the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, and the Center for Devices and Radiological Health;

(2) describe the actions the Secretary will take to recruit, retain, train, and continue to develop the workforce at the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, and the Center for Devices and Radiological Health to fulfill the public health mission of the Food and Drug Administration; and

(3) identify results-oriented, outcome-based measures that the Secretary will use to measure the progress of achieving the strategic goals and priorities identified under paragraph (1) and the effectiveness of the actions identified under paragraph (2), including metrics to ensure that managers and reviewers of the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, and the Center for Devices and Radiological Health are familiar with and appropriately and consistently apply the requirements under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), including new requirements under the 2012 user fee agreements.

(b) REPORT.—Not later than January 1, 2016, the Comptroller General of the United States shall issue a report regarding the strategic management plan described in subsection (a) and related actions carried out by the Food and Drug Administration. Such report shall—

(1) assess the effectiveness of the actions described in paragraph (2) in recruiting, retaining, training, and developing the workforce at the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, and the Center for Devices and Radiological Health in fulfilling the

public health mission of the Food and Drug Administration;

(2) assess the effectiveness of the measures identified under paragraph (2) in gauging progress against the strategic goals and priorities identified under paragraph (1);

(3) assess the extent to which the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, and the Center for Devices and Radiological Health are using the identified results-oriented set of performance measures in tracking their workload by strategic goals and the effectiveness of such measures;

(4) assess the extent to which performance information is collected, analyzed, and acted on by managers; and

(5) make recommendations, as appropriate, regarding how the strategic management plan and related actions of the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, and the Center for Devices and Radiological Health could be improved to fulfill the public health mission of the Food and Drug Administration in as efficient and effective manner as possible.

SEC. 602. INDEPENDENT ASSESSMENT.

(a) IN GENERAL.—The Secretary shall contract with a private, independent consulting firm capable of performing the technical analysis, management assessment, and program evaluation tasks required to conduct a comprehensive assessment of the process for the review of drug applications under subsections (b) and (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b), (j)) and subsections (a) and (k) of section 351 of the Public Health Service Act (42 U.S.C. 262(a), (k)). The assessment shall address the premarket review process of drugs by the Food and Drug Administration, using an assessment framework that draws from appropriate quality system standards, including management responsibility, documents controls and records management, and corrective and preventive action.

(b) PARTICIPATION.—Representatives of the Food and Drug Administration and manufacturers of drugs subject to user fees under part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g et seq.) shall participate in a comprehensive assessment of the process for the review of drug applications under section 505 of the Federal Food, Drug, and Cosmetic Act and section 351 of the Public Health Service Act. The assessment shall be conducted in phases.

(c) FIRST CONTRACT.—The Secretary shall award the contract for the first assessment under this section not later than March 31, 2013. Such contractor shall evaluate the implementation of recommendations and publish a written assessment not later than February 1, 2016.

(d) FINDINGS AND RECOMMENDATIONS.—

(1) IN GENERAL.—The Secretary shall publish the findings and recommendations under this section that are likely to have a significant impact on review times not later than 6 months after the contract is awarded. Final comprehensive findings and recommendations shall be published not later than 1 year after the contract is awarded.

(2) IMPLEMENTATION PLAN.—The Food and Drug Administration shall publish an implementation plan not later than 6 months after the date of receipt of each set of recommendation.

(e) SCOPE OF ASSESSMENT.—The assessment under this section shall include the following:

(1) Identification of process improvements and best practices for conducting predictable, efficient, and consistent premarket reviews that meet regulatory review standards.

(2) Analysis of elements of the review process that consume or save time to facilitate a more efficient process. Such analysis shall include—

(A) consideration of root causes for inefficiencies that may affect review performance and total time to decision;

(B) recommended actions to correct any failures to meet user fee program goals; and

(C) consideration of the impact of combination products on the review process.

(3) Assessment of methods and controls of the Food and Drug Administration for collecting and reporting information on premarket review process resource use and performance.

(4) Assessment of effectiveness of the reviewer training program of the Food and Drug Administration.

(5) Recommendations for ongoing periodic assessments and any additional, more detailed or focused assessments.

(f) REQUIREMENTS.—The Secretary shall—

(1) analyze the recommendations for improvement opportunities identified in the assessment, develop and implement a corrective action plan, and ensure it effectiveness;

(2) incorporate the findings and recommendations of the contractors, as appropriate, into the management of the premarket review program of the Food and Drug Administration; and

(3) incorporate the results of the assessment in a Good Review Management Practices guidance document, which shall include initial and ongoing training of Food and Drug Administration staff, and periodic audits of compliance with the guidance.

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